ARC 6178C

PHARMACY BOARD[657]

Notice of Intended Action

Proposing rule making related to compounded preparations and providing an opportunity for public comment

The Board of Pharmacy hereby proposes to amend Chapter 20, "Compounding Practices," Iowa Administrative Code.

Legal Authority for Rule Making

This rule making is proposed under the authority provided in Iowa Code section 147.76.

State or Federal Law Implemented

This rule making implements, in whole or in part, Iowa Code section 147.76.

Purpose and Summary

These proposed amendments would allow veterinarians who have obtained compounded preparations for office stock use to dispense the compounded preparations to the owner of a veterinary patient to treat an immediate medical need when timely access to a patient-specific supply of compounded medication is not available, no commercially available product can meet the need of the patient, lack of treatment will likely result in patient harm, and the supply does not exceed 14 days.

Fiscal Impact

This rule making has no fiscal impact to the State of Iowa.

Jobs Impact

After analysis and review of this rule making, no impact on jobs has been found.

Waivers

Any person who believes that the application of the discretionary provisions of this rule making would result in hardship or injustice to that person may petition the Board for a waiver of the discretionary provisions, if any, pursuant to 657—Chapter 34.

Public Comment

Any interested person may submit written comments concerning this proposed rule making. Written comments in response to this rule making must be received by the Board no later than 4:30 p.m. on March 1, 2022. Comments should be directed to:

Sue Mears
Board of Pharmacy
400 S.W. 8th Street, Suite E
Des Moines, Iowa 50309
Email: sue.mears@iowa.gov

Public Hearing

No public hearing is scheduled at this time. As provided in Iowa Code section 17A.4(1)"b," an oral presentation regarding this rule making may be demanded by 25 interested persons, a governmental

subdivision, the Administrative Rules Review Committee, an agency, or an association having 25 or more members.

Review by Administrative Rules Review Committee

The Administrative Rules Review Committee, a bipartisan legislative committee which oversees rule making by executive branch agencies, may, on its own motion or on written request by any individual or group, review this rule making at its regular monthly meeting or at a special meeting. The Committee's meetings are open to the public, and interested persons may be heard as provided in Iowa Code section 17A.8(6).

The following rule-making actions are proposed:

ITEM 1. Amend rule **657—20.2(124,126,155A)**, definition of "Office use," as follows:

"Office use" means that a compounded product has been prepared and distributed to a practitioner for administration to a patient by the practitioner in the course of the practitioner's professional practice. A compounded product distributed to a practitioner for "office use" shall not require a patient-specific prescription and may not be further distributed to another practitioner or dispensed to a patient for self-administration, except as provided in subrule 20.15(2).

ITEM 2. Amend rule 657—20.15(124,126,155A) as follows:

657—20.15(124,126,155A) Compounding for office use.

20.15(1) No change.

20.15(2) *Veterinary compounded preparations.* Veterinary compounded preparations may be sold to a practitioner for office use if the preparations are compounded by an Iowa-licensed pharmacy or outsourcing facility and sold directly to the practitioner by the pharmacy or outsourcing facility. Veterinary compounded preparations sold to a practitioner for office use may be dispensed to the owner of a veterinary patient to treat an immediate medical need when timely access to a patient-specific supply of compounded medication is not available, no commercially available product can meet the need of the patient, lack of treatment will likely result in patient harm, and the supply does not exceed 14 days.

20.15(3) *Office use.* Compounded preparations distributed for office use pursuant to subrule 20.15(1) or 20.15(2) and in accordance with the labeling requirements of subrule 20.15(4) do not require a patient-specific prescription but do require that the compounded preparation be administered to a patient in the course of the practitioner's professional practice. Compounded preparations distributed for office use pursuant to this rule shall not be further distributed to other practitioners or dispensed to a patient for self-administration, except as provided in subrule 20.15(2).

20.15(4) No change.